Clinical trials in general practice

CLINICAL trials are becoming more common in general practice. Many general practitioners will recall that only a few years ago they were being asked to take part in open trials—where there was no comparison with other drugs nor any attempt to carry out the investigation blind—and were rewarded by pieces of equipment for doing so. These trials produced a lot of criticism about both method and motives and were often rightly identified as concealed marketing. The doctor became used to prescribing drug X and some patients went on receiving it long after the trial was finished.

There are a number of reasons why it is necessary for good quality trials to be carried out in general practice. Some illnesses, and not only minor ones, are now managed almost entirely in general practice, which has become the only field from which suitable patients can be obtained. Patients live in a much less controlled environment than hospital patients and, if this is where they are going to take their drugs after a trial has finished, it may be important to observe the drug's action in this situation. Selection of controls and observation of the long-term action of drugs may also be easier in general practice than in hospital practice.

Clinical trials may be carried out at a number of different phases in the development of a drug and the guide-lines laid down by the US Food and Drug Administration are usually followed. Phase I trials are designed to look at the pharmacodynamics and metabolic activity of the drug under scrutiny and are usually carried out on a small number of volunteers or selected patients.

Phase II trials have rigidly designed protocols and are more concerned with drug safety and efficacy in very closely monitored patients. The dividing line between these and Phase III trials is somewhat blurred, but the latter complete the collection of data about efficacy, safety tolerance and adverse effects. These trials are all carried out before the drug is licensed for marketing. Phase IV trials take place after marketing and include additional studies on adverse reactions, comparison with other forms of treatment and long-term studies on morbidity and mortality. In a way, therefore, the first three phases of trials are looking mostly at the drugs and the last phase more at the patient. The design of the trial will clearly depend upon which phase it falls into, and general practitioners must realize that the requirement of one type of trial will be very different from another and that Phase II and III trials will involve the collection of many more data than the normal clinical situation requires.

A joint working party of the Association of the British Pharmaceutical Industry, the British Medical Association and the College has recently produced a Code of Practice for Clinical Trials in General Practice (*British Medical Journal,* in press). It may require some minor amendments to the terms and conditions of service of the doctor and these are being discussed with the Department of Health and Social Security. It is to be published shortly and all general practitioners should pay careful attention to it. It seeks to ensure that clinical trials carried out in general practice will be of the highest scientific standard, that the pharmaceutical industry in this country can remain in the forefront as innovators and that the position of the patient is secured. A recent issue of the *Drug and Therapeutics Bulletin* (1981) has outlined some of the issues and can form a useful check for the general practitioner invited to take part in a trial.

The establishment of the Medicines Surveillance Centre (*Journal of the Royal College of General Practitioners,* 1981) by this College underlines the importance we give to drug trials and the need for motivated general practitioners to take part in well-designed trials. Participation is not, however, a step to take lightly. The degree of commitment required to produce good and reliable data is considerable.

A further topic under consideration in recent months has been the establishment of a network of suitably constituted ethical committees to which general practitioner trials can be referred. The BMA and the College have proposed a model constitution and course of action for these committees (*British Medical Journal,* 1981) and a number of general practitioners will now be invited to work on them. They will develop expertise in the careful evaluation of protocols.

These developments mark another step forward for general practice and are to be welcomed. Clinical trials

in general practice are necessary and important. They are not for all general practitioners; some will not have an interest in this form of research and others will feel they do not have enough time, but fortunately there are many who will want to provide this important service.

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Switch on to patient education

SHOULD general practitioners be required to watch television as part of their job of patient care? With the increase in the number of television programmes designed to change patient behaviour, and the decision of this journal to publish details of such programmes (News and Views, page 256), it may well be the case that the general practitioner who is unaware of the messages being directed to his patients will be hampered in discussion of the sort of preventive topics that are the subject of such programmes.

This would only be true, of course, if the programmes are effective. Until recently, the policy of television controllers in tucking such programmes into ghetto slots operation between the broadcast media and general practitioners. For such co-operation to be successful, however, the media have to be taken seriously and on their own terms. Doctors sometimes give the impression that when it comes to medical programmes no one is able to decide on content, style and priorities other than a person who has been through seven years of medical training. The time, effort and skills that go into some of the major projects now being produced by the media are every bit as professional as the medical profession's activities in the area of patient education, which have not in any case been consistently successful. However low a priority television viewing has in the average